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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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IPLA P.A.
3580 WILSHIRE BLVD.
17TH FLOOR
LOS ANGELES, CA 90010

EXAMINER
CRUZ, KATHRIEN ANN

ART UNIT	PAPER NUMBER
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/598,159	YOON, JI-WON	
	Examiner	Art Unit	
	KATHRIEN CRUZ	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 7-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 7--21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/16/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-5 and 7-21 are pending.

Priority

This application is 317 of PCT/KR05/00445 (dated 02/17/2005).

which claims foreign priority date of 02/18/2004.

Claim Rejections - 35 USC § 101

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Claims 7-11are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e. results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example Exparte Dunki, 153 USPQ 678 (Bd.App. 1967) and Clinical Products, Ltd, v. Brenner, 255 F. Supp. 131,149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-11are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claims 1-5 and 7-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of a cold with the administration of vitamin C and ginkgetin, does not reasonably provide enablement for the **prevention** or **prophylactically** treatment of a cold.

Enablement is considered in view of the Wands factors (MPEP 2164.01(A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art, predictability of the art and the amount of experimentation necessary. All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the Invention: Claims 1-5 and 7-21 are drawn to a composition and method of treating or **preventing** a cold administering a **prophylactically** effective amount of vitamin C and ginkgetin.

Breadth of the claims: The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims. The claims encompass prevention of a cold. Applicants claim that not only can a treated with vitamin C and

ginkgetin, but that it can also be **prevented** with **prophylactically** effective amount of vitamin C and ginkgetin.

Guidance of the Specification/Working Examples: Applicant has provided no guidance showing the actual "prevention" with prophylactic treatment of a cold. All the guidance are directed to the treatment of a cold than the prevention.

State of the Art: *While the state of the art is relatively high with regard to the* ***treatment of the*** symptoms of a cold, the state of the art with regard to **prevention** of all colds is underdeveloped. Therefore it is highly speculative that a cold is preventable as claimed.

Predictability/Unpredictability in the Art: There *is a general lack of predictability in the pharmaceutical art. In re Fisher, 427, F. 2d 833, 166, USPQ 18 (CCPA 1970). It would be unpredictable for the skilled artisan to use the claimed formulation to prevent all forms of a cold because of the reasons stated above.*

The Quantitation of Experimentation Required: In order to practice Applicants invention, it would be necessary for one to conduct an exhaustive amount of experiments. Applicant would need to provide reasonable data showing that vitamin C and ginkgetin and Vitamin A, B_1, E, D and B can **prevent** a cold. Therefore, in order to practice the claimed invention, the amount of experimentation required would be considered undue and burdensome.

According, the method of **preventing** a cold with a **prophylactically** amount of vitamin C and ginkgetin is not enabled by the instant specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1 and 4 are rejected under 35 U.S.C. 102(a) as being anticipated by Stuckler (U.S. Patent 6,605,296).

Stuckler teaches that for thousands of years the gingko has been used as a medicinal plant in China. The gingko biloba leaves contain bioactive plant substances: flavonol glycosides, bisflavonoids (for example **ginkgetin**), ginkgolides, bilobalide (terpene lactones) and procyanidines. As an antioxidative radical trap gingko biloba leaf extract prevents lipid peroxidation by neutralization of toxic oxygen radicals. It improves the flow properties of the blood via reduction of thrombocyte and erythrocyte (aggregation and via reduction of blood viscosity. It promotes oxygen absorption and use in the tissue (all of the above is found in column 4, lines 35-50). Stuckler teach the addition **of vitamin C, B_1, B, and D** with parts by weight in examples 2 and 3. Stuckler teaches that vitamin C (ascorbic acid) is in the amount of 0.02 to 0.2), Vitamin B_1 is in the amount of 0.002 to 0.01, Vitamin B is in the amount of 0.005 to 0.05, Vitamin D is in the amount of 2.5 micrograms. Stuckler teaches that tocopherol (**vitamin E)** (preferably 0.05 to 0.2 parts by weight) contains the diterpene phytol in the side chain (which is composed of four isoprene units). It occurs naturally in olive oil. (column 3, lines 24-

27). Stuckler discloses that milk may be added to the composition in which mild would contain vitamin D (column 11, lines 44-47). Stuckler teaches that a composition of vitamins boost the immune systems against a variety of ailments (e.g. cancer, cardiac, circulatory and rheumatic conditions)(column 2, lines 32-35)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2, 5, 12-13, 15-18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stuckler (U.S. Patent 6,605,296) as applied to claims 1 and 4 above, and further in view of Cho et al (Korean Patent Abstract 1020010088727) of record.

Stuckler as cited above.

Stuckler does not expressly teach the treatment of a cold or the instant claimed percentages by weight of gingetin, Vitamin C, A, D, B_1, B, E.

Cho teaches that certain vitamins (e.g. Vitamin A, Vitamin C and Vitamin E) are useful the treatment of colds and superior in the repression of influenza virus.

It would have been obvious to one of ordinary skills in the art to employ the teachings of Cho to that of Stuckler in the treatment of a cold because it is known that Vitamins (e. g. Vitamin A, Vitamin C and Vitamin E) are known to enhance the immune system and to treat colds and influenza as taught by Cho. One would be motivated to treat colds with ginkgetin and Vitamin C, Vitamin A, Vitamin B_1, Vitamin B, Vitamin D, Vitamin E, because of the enhancement to the immune system which allows one's system to combat viruses such as colds and influenza. A composition of ginkgetin and a variety of Vitamins as taught by Stuckler would demonstrate an additive effect in the treatment of colds by augmenting the immune system to overpower such viruses.

With regards to the claimed percentages of Ginkgetin, Vitamin C, Vitamin A, Vitamin B_1, Vitamin B, Vitamin D, Vitamin E. It is well within the scope of an artisan to adjust the dosages of the active agents to address the needs of each individual patient. As anyone of ordinary skill in the art will appreciate, preferred dosages are merely exemplary and serve as useful guideposts for the physician. There are, however, many reasons for varying dosages, including by orders of magnitude; for instance, an extremely heavy patient or one having an unusually severe infection would require a correspondingly higher dosage. Furthermore, it is routine during animal and clinical studies to dramatically vary dosage to obtain data on parameters such as toxicity. The

specific safe and effective amount will be vary, with such factors as the particular condition being treated, the physical condition of the patient, the duration of treatment , the nature of the concurrent therapy (if any), the specific dosage form to be used, the carrier employed, the solubility of the formula therein and the dosage regimen desired for the composition. Furthermore, it is obvious to vary and/or optimize the amount of (compound) provided in the composition, according to the guidance provided by (reference), to provide a composition having the desired properties such as the desired (ratios, concentrations, percentages, etc.). It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Claims 3, 14, 19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stuckler (U.S. Patent 6,605,296) and Cho et al (Korean Patent Abstract 1020010088727) of record as applied to claims 2, 5, 12-13, 15-18 and 20 above, and further in view of Merck Index (Thirteenth Edition, 2001, pg 1021-1022).

Stuckler and Cho as cited above.

Neither Stukler nor Cho expressly teach the addition of maltol.

The Merck Index teaches that maltol is flavoring agent used to impart a "freshly baked" order and flavor to bread and cakes.

It would have been obvious to one of ordinary skills in the art at the time of the invention to employ maltol to composition of ginkgetin and Vitamin C, Vitamin A, Vitamin

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B_1, Vitamin B, Vitamin D, Vitamin E, because the addition of flavoring is pleasing for the subject and would entice the subject to take the composition.

Deleted: masks the bitter taste of the ginkgetin

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Deleted: {Do you know if ginkgetin is bitter? How do you know?} ¶

Deleted: {San, the declaration would have to be dated back to 1999, because Stuckler orginal WO is in German and entered National in 2000, which is the date that we have, 06/14/2000, this was NOT easy art to find, especially that explained the orgins of ginkgetin as clearly as Stuckler}¶

Conclusion

Claims 1-5, 7-21 are rejected.

No claims are allowed.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHRIEN CRUZ whose telephone number is (571)270-5238. The examiner can normally be reached on Mon - Thurs 7:00am - 5:00pm with every Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KATHRIEN CRUZ/
Examiner, Art Unit 1617

/San-ming Hui/
Primary Examiner, Art Unit 1617

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